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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,174	08/28/2003	J. Wallace Parce	100/06341	5968

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EXAMINER

TRAN, MY CHAU T

ART UNIT PAPER NUMBER

1639

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/650,174		PARCE ET AL.	
	Examiner		Art Unit	
	MY-CHAU T. TRAN		1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application and Claims Status

1. Applicants' amendment and response filed 02/27/2006 are acknowledged and entered.
2. Claims 1-28 were pending. Applicants have cancelled claim 28 and the first line of the instant specification. No claims were amended and/or added. Therefore, claims 1-27 are currently pending.

Withdrawn Objection(s) and /or Rejection(s)

3. The objection to the instant specification because it did not include the status of the prior application has been withdrawn in light of applicant's arguments (see page 7, paragraph IV, filed 03/02/2006) and amendments of the specification.
4. The rejection of claims 1-27 under 35 USC 102(e) as being anticipated by Parce et al. (US Patent 6,274,337 B1; *filling date of 03/19/1998*) has been withdrawn in light of applicant's arguments, see page 11, filed 03/02/2006.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. *The instant invention recites a method of detecting a binding activity. The method comprises the steps of a) flowing a first component or a set of first components through a*

first channel concomitant with a second component or a set of second components through the first channel; b) the second component or the set of second components binds to the first component or the set of first components; and c) detecting a detectable signal that indicates a final concentration of the at least one first component or the set of first components that remains unbound after exiting from the first channel, thereby detecting the binding activity.

The limitation that first channel comprises a mixing longitudinal segment is interpreted as a structural limitation of the first channel.

The limitations that the first component or the set of first components 1) diffuses more rapidly in solution than the at least one second component or the set of second components, and 2) diffuses substantially across the first channel in the mixing longitudinal segment are interpreted as functional limitations of the first component or the set of first components.

The limitation that the second component or the set of second components diffuses less than substantially across the first channel in the mixing longitudinal segment is interpreted as functional limitation of the second component or the set of second components.

7. Claims 1, 3, 13-15, 18-20, 21, 23, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Yager et al. (US Patent 5,716,852).

Yager et al. disclose a system and methods for detecting the presence of analyte particles in a sample stream (see e.g. Abstract; col. 1, lines 10-16; col. 3, lines 17-36; col. 5, lines 38-54). In one type method disclosed by Yager et al., the method comprises the steps of 1) conducting the sample (refers to instant claimed second component) stream and an indicator (refers to instant claimed first component) stream into a laminar flow channel (refers to instant claimed first channel) such that the sample stream and indicator stream flow in adjacent laminar streams in the laminar flow channel (refers to instant claimed step (a)); 2) allowing the analyte particles of the sample stream to diffuse into the indicator stream such that the analyte particles causes a detectable change in property of the indicator substance in the indicator stream (refers to instant claimed step (b) and instant claimed functional limitations of the first and second components); 3) detecting the concentration of the analyte by measuring the signal of the indicator stream

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before and after diffusion of the analyte particles into the indicator stream (refers to instant claimed step (c) and instant claim 21)(see e.g. col. 3, lines 5-16, and 50-67; col. 5, line 39 thru col. 6, line 20; col. 10, lines 34-42) . The diffusion of the analyte particles into the indicator stream is perpendicular to the flow of the direction (see e.g. col. 7, lines 53-61). The sample stream comprises analyte particles such as blood cell (refers to instant claim 15) and the molecular weight of less than 1,000,000 MW (refers to instant claims 18 and 19)(see e.g. col. 4, lines 4-19). The indicator stream comprises indicator substance such as organic molecule (refers to instant claim 3)(see e.g. col. 3, lines 50-67; col. 4, lines 20-31). The laminar flow channel comprises a length to permit small analyte particles to diffuse from the sample stream and a depth to allow flow of two streams (refers to instant structural limitations of the first channel and instant claim 23)(see e.g. col. 4, lines 49-67). The detection signal includes fluorescence (refers to instant claim 27)(see e.g. col. 3, lines 50-67). The fluid flow through the device comprises means for applying pressure to the flow of the fluid (refers to instant claim 20)(see e.g. col. 10, lines 5-19). Additionally, the features of remaining dependent claims, i.e. claims 13 and 14, are either specifically described by the reference (e.g. diffusion coefficient, see e.g. col. 10, lines 44-51), or constitute obvious variations in parameters which are routinely modified in the art, and which have not been described as critical to the practice of the invention.

Therefore, the system and method of Yager et al. anticipates the presently claimed invention.

Response to Arguments

8. Applicant's arguments directed to the above 102(b) rejection were considered but they are not persuasive for the following reasons.

[1] Applicant contends that Yager et al. do not teach the claimed limitation of *'flowing at least one second component or a set of second components through the first channel wherein the at least one second component or the set of second components diffuses less than substantially across the first channel in the mixing longitudinal segment'*.

[2] Applicant alleges that Yager et al. do not teach the claimed limitation of *'detecting a detectable signal that indicates a final concentration of the at least one first component or the set of first components that remains unbound after exiting from the first channel, thereby detecting the binding activity'*.

Thus, the reference of Yager et al. do anticipates the presently claimed invention.

This is not found persuasive for the following reasons:

[1] It is the examiner's position is that Yager et al. do teach the claimed limitation of *'flowing at least one second component or a set of second components through the first channel wherein the at least one second component or the set of second components diffuses less than substantially across the first channel in the mixing longitudinal segment'*. Yager et al. do teach the method step of conducting the sample stream (refers to instant claimed second component) into a laminar flow channel (refers to instant claimed first channel), i.e. *'flowing at least one second component through the first channel'* (col. 3, lines 5-16; col. 5, lines 39-54). In addition, Yager et al. disclose that *'as is known in the art, the diffusion coefficient for the analyte particles is inversely related to the size of the particle. Once the diffusion coefficient for the particles desired to be detected is known, the contact time of the two streams, size of the central channel, relative volumes of the streams, pressure and velocities of the streams can be adjusted to achieve the desired diffusion pattern'* (col. 10, lines 46-52), i.e. the diffusion rates of the particles are a

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choice of experimental design. As a result the instant claimed limitation of *'wherein the at least one second component or the set of second components diffuses less than substantially across the first channel in the mixing longitudinal segment'* is considered within the purview of the cited prior art. Consequently, Yager et al. do teach the claimed limitation of *'flowing at least one second component or a set of second components through the first channel wherein the at least one second component or the set of second components diffuses less than substantially across the first channel in the mixing longitudinal segment'*.

[2] It is the examiner's position is that Yager et al. do teach the claimed limitation of *'detecting a detectable signal that indicates a final concentration of the at least one first component or the set of first components that remains unbound after exiting from the first channel, thereby detecting the binding activity'*. Yager et al. disclose that the an indicator stream comprises indicator substance (refers to instant claimed first component), which indicates the presence of the analyte particles by a detectable change in property when contacted with particles of said analyte and the method step of detecting the change comprises a) *'providing means for conducting specimen streams from the indicator stream at successive intervals along the length of the laminar flow channel, such as smaller channels equipped with viewports as described herein'* (col. 6, lines 12-15), i.e. taking a sample of the indicator substance from the indicator stream at various point along the laminar flow channel to measure the changes in the intensity of the signal such that the concentration of analyte particles in the sample of the sample stream can be calculated. In which case the "unbound" indicator substance are being detected.

Accordingly, Yager et al. do teach the claimed limitation of *'detecting a detectable signal that*

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indicates a final concentration of the at least one first component or the set of first components that remains unbound after exiting from the first channel, thereby detecting the binding activity'.

Therefore, the system and method of Yager et al. anticipates the presently claimed invention, and the rejection is maintained.

9. Claims 1, 3, 13-15, 20, 23, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al. (US Patent 6,221,677 B1; *effective filling date of 09/26/1997*).

Wu et al. disclose apparatus and methods for detecting the presence of analyte particles in a sample fluid (see e.g. Abstract; col. 1, lines 11-17, and 54-62; col. 2, lines 45-56). In one type method disclosed by Wu et al., the competitive immunoassays method comprises the steps of 1) flowing the sample stream containing native antigens (refers to instant claimed second component and instant claim 15) and the reagent stream containing antibodies bound to fluorescently labeled antigen (refers to instant claimed first component and instant claim 3) into a laminar flow channel (refers to instant claimed first channel) such that the sample stream and indicator stream flow in adjacent laminar streams in the reaction channel (refers to instant claimed step (a)); 2) allowing the native antigens to diffuse into the reagent stream and displace the fluorescently labeled antigens (refers to instant claimed step (b) and instant claimed functional limitations of the first and second components); 3) detecting the amount of free and bound fluorescently labeled antigens (refers to instant claimed step (c))(see e.g. col. 2, lines 45-56; col. 6, lines 14-23; col. 7, lines 31-46). The laminar flow channel comprises a length to permit small analyte particles to diffuse from the sample stream and a depth to allow flow of two streams (refers to instant structural limitations of the first channel and instant claim 23)(see e.g.

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col. 12, lines 31-39). The detection signal includes fluorescence (refers to instant claim 27)(see e.g. col. 2, lines 45-56; col. 6, lines 34-50). The fluid flow through the device comprises means for applying pressure to the flow of the fluid (refers to instant claim 20)(see e.g. col. 12, lines 40-49). Additionally, the features of remaining dependent claims, i.e. claim 13 and 14, are either specifically described by the reference (e.g. diffusion coefficient, see e.g. col. 10, lines 44-51), or constitute obvious variations in parameters which are routinely modified in the art, and which have not been described as critical to the practice of the invention.

Therefore, the system and method of Wu et al. anticipates the presently claimed invention.

Response to Arguments

10. Applicant's arguments directed to the above 102(e) rejection were considered but they are not persuasive for the following reasons.

[1] Applicant alleges that Wu et al. do not teach the claimed limitation of '*flowing at least one second component or a set of second components through the first channel wherein the at least one second component or the set of second components diffuses less than substantially across the first channel in the mixing longitudinal segment*'.

[2] Applicant argues that Wu et al. do not teach the claimed limitation of '*detecting a detectable signal that indicates a final concentration of the at least one first component or the set of first components that remains unbound after exiting from the first channel, thereby detecting the binding activity*'.

This is not found persuasive for the following reasons:

[1] It is the examiner's position is that Wu et al. do teach the claimed limitation of *'flowing at least one second component or a set of second components through the first channel wherein the at least one second component or the set of second components diffuses less than substantially across the first channel in the mixing longitudinal segment'*. Wu et al. do teach the method step of flowing the sample stream containing native antigens (refers to instant claimed second component) into a laminar flow channel (refers to instant claimed first channel)(col. 2, lines 45-56), i.e. *'flowing at least one second component through the first channel'*. In addition, Wu et al. disclose that the diffusion coefficient for the analyte is inversely related to the size of the analyte (col. 10, lines 35-37) such that the desired diffusion pattern can be obtained by adjusting the channels configuration, flow velocity, and contact time between the sample stream and the reagent stream (col. 11, lines 4-15), i.e. the diffusion rates of the analyte are a choice of experimental design. As a result the instant claimed limitation of *'wherein the at least one second component or the set of second components diffuses less than substantially across the first channel in the mixing longitudinal segment'* is considered within the purview of the cited prior art. Consequently, Wu et al. do teach the claimed limitation of *'flowing at least one second component or a set of second components through the first channel wherein the at least one second component or the set of second components diffuses less than substantially across the first channel in the mixing longitudinal segment'*.

[2] It is the examiner's position is that Wu et al. do teach the claimed limitation of *'detecting a detectable signal that indicates a final concentration of the at least one first component or the set of first components that remains unbound after exiting from the first channel, thereby detecting the binding activity'*. Wu et al. disclose the method step of allowing

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the native antigens to diffuse into the reagent stream and displace the fluorescently labeled antigens from the antibodies, i.e. the fluorescently labeled antigens bound to the antibodies becomes free (unbound)(col. 2, lines 49-56), and detecting the free fluorescently labeled antigens (col. 2, line 67 thru col. 3, line 4). As a result, Wu et al. do teach the claimed limitation of *'detecting a detectable signal that indicates a final concentration of the at least one first component or the set of first components that remains unbound after exiting from the first channel, thereby detecting the binding activity'*.

Therefore, the system and method of Wu et al. anticipates the presently claimed invention, and the rejection is maintained.

Allowable Subject Matter

11. Claims 2, 4-12, 16-17, 22, and 24-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
May 4, 2006

PETER PARAS, JR.
PRIMARY EXAMINER

Peter Paras Jr.
SPE 1639